IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD., and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.,	)	
Plaintiffs,	)	
v.	)	C. A. No. 16-924-SLR
ZYDUS PHARMACEUTICALS (USA), INC. and CADILA HEALTHCARE LTD. (d/b/a ZYDUS CADILA),	)	
Defendants.	)	

DEFENDANTS' ANSWER TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Cadila Healthcare Limited ("Cadila") (collectively, "Defendants") for their Answer and Affirmative Defenses to the Complaint of Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. ("Plaintiffs" or "Astellas") state as follows:

All averments not expressly admitted are denied.

THE PARTIES

1. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 1 and therefore deny them.

2. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore deny them.

3. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore deny them.

4. Defendants admit that Zydus USA is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. Defendants further admit that Zydus USA files Abbreviated New Drug Applications ("ANDAs") seeking U.S. Food and Drug Administration ("FDA") approval to market pharmaceutical products and that Zydus USA sells pharmaceutical products, including generic pharmaceutical products, in the United States. Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 209488. Defendants deny all other allegations in paragraph 4.

5. Defendants admit that Cadila is an Indian company having its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India. Defendants admit that Cadila develops and manufactures pharmaceutical products, including generic pharmaceutical products that are sold by Zydus USA in the United States. Defendants do not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 209488. Defendants deny all other allegations in paragraph 5.

6. Defendants admit that the parent corporation of Zydus Pharmaceuticals (USA) Inc. is Zydus International Pvt. Ltd. Ireland, which is owned by Cadila Healthcare Limited. Defendants deny all other allegations in paragraph 6.

7. The allegations in paragraph 7 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted to FDA ANDA No. 209488, seeking approval to engage in the commercial manufacture, use or sale

of mirabegron extended-release oral tablets, 25 mg and 50 mg, manufactured by Cadila. Defendants deny all other allegations in paragraph 7.

NATURE OF ACTION

8. The allegations in paragraph 8 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs' Complaint purports to be a civil action alleging infringement of United States Patent Nos. 7,342,117 ("the '117 patent"), 7,982,049 ("the '049 patent"), 8,835,474 ("the '474 patent") and RE44,872 ("the '872 patent") pursuant to Title 35 of the United States Code. Defendants admit that Zydus USA submitted to FDA ANDA No. 209488 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of mirabegron extended-release oral tablets, 25 mg and 50 mg. Defendants deny that they have infringed any valid claim of the '117 patent, the '049 patent, the '474 patent or the '872 patent. Defendants deny all other allegations in paragraph 8.

JURISDICTION AND VENUE

9. The allegations in paragraph 9 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this Court solely for purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 209488. Defendants deny all other allegations in paragraph 9.

10. The allegations in paragraph 10 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 209488. Defendants deny all other allegations in paragraph 10.

11. The allegations in paragraph 11 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 209488. Defendants admit that the parent corporation of Zydus Pharmaceuticals (USA) Inc. is Zydus International Pvt. Ltd. Ireland, which is owned by Cadila Healthcare Limited. Defendants deny all other allegations in paragraph 11.

12. The allegations in paragraph 12 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 209488. Defendants admit that the parent corporation of Zydus Pharmaceuticals (USA) Inc. is Zydus International Pvt. Ltd. Ireland, which is owned by Cadila Healthcare Limited. Defendants deny all other allegations in paragraph 12.

13. The allegations in paragraph 13 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA files ANDAs seeking FDA approval to market pharmaceutical products and that Zydus USA sells pharmaceutical products in the United States, including pharmaceutical products manufactured by Cadila. Defendants do not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 209488. Defendants deny all other allegations in paragraph 13.

14. Defendants admit that Cadila develops and manufactures pharmaceutical products, including generic pharmaceutical products. Defendants further admit that Zydus USA files ANDAs seeking FDA approval to market pharmaceutical products and that Zydus USA sells pharmaceutical products in the United States, including products manufactured by Cadila. Defendants admit that Zydus USA submitted to FDA ANDA No. 209488 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use or sale of mirabegron extended-release oral tablets, 25 mg and 50 mg, manufactured by Cadila. Defendants do not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed products described in ANDA No. 209488. Defendants deny all other allegations in paragraph 14.

15. Defendants admit that Zydus USA submitted to FDA ANDA No. 209488 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use or sale of mirabegron extended-release oral tablets, 25 mg and 50 mg, manufactured by Cadila and that ANDA No. 209488 included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '117 patent, the '049 patent, '474 patent and the '872 patent. Defendants deny all other allegations in paragraph 15.

16. Defendants admit that Zydus USA transmitted a letter dated September 6, 2016 to Astellas Pharma Global Development, Inc. and Astellas Pharma Inc. notifying Astellas Pharma Global Development, Inc. and Astellas Pharma Inc. that Zydus USA submitted to FDA ANDA No. 209488 under 21 U.S.C. § 355(j), which included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '117 patent, the '049 patent, '474 patent and the '872 patent ("Zydus USA's September 6, 2016 letter"). Defendants deny all other allegations in paragraph 16.

17. Denied.

18. The allegations in paragraph 18 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Cadila is an Indian company having its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India. Defendants admit that Cadila develops and manufactures pharmaceutical products, including pharmaceutical products sold in the United States. Defendants do not contest personal jurisdiction in this Court solely for Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 209488. Defendants deny all other allegations in paragraph 18.

19. The allegations in paragraph 19 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court solely for purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to the proposed product described in ANDA No. 209488. Defendants deny all other allegations in paragraph 19.

FACTUAL BACKGROUND

A. The '117 Patent

20. Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 7,342,117 is attached to the Complaint as Exhibit A. Defendants further admit that Exhibit A is entitled "α-Form or β-Form Crystal of Acetanilide Derivative" and lists March 11, 2008 as the Date of Patent. Defendants deny all other allegations in paragraph 20.

21. The allegations in paragraph 21 state legal conclusions to which no answer is required. To the extent that an answer is required, Defendants deny that the allegations

accurately and completely recite the limitations of the claims recited in the '117 patent and, therefore, deny the allegations in paragraph 21.

22. Defendants admit that the FDA's Orange Book lists the '117 patent in connection with New Drug Application ("NDA") No. 202611 with an expiration date of November 4, 2023. Defendants deny all other allegations in paragraph 22.

B. The '049 Patent

23. Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 7,982,049 is attached to the Complaint as Exhibit B. Defendants further admit that Exhibit B is entitled "α-Form or β-Form Crystal of Acetanilide Derivative" and lists July 19, 2011 as the Date of Patent. Defendants deny all other allegations in paragraph 23.

24. The allegations in paragraph 24 state legal conclusions to which no answer is required. To the extent that an answer is required, Defendants deny that the allegations accurately and completely recite the limitations of the claims recited in the '049 patent and, therefore, deny the allegations in paragraph 24.

25. Defendants admit that the FDA's Orange Book lists the '049 patent in connection with NDA No. 202611 with an expiration date of November 4, 2023. Defendants deny all other allegations in paragraph 25.

C. The '474 Patent

26. Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. 8,835,474 is attached to the Complaint as Exhibit C. Defendants further admit that Exhibit C is entitled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient" and lists September 16, 2014 as the Date of Patent. Defendants deny all other allegations in paragraph 26.

27. The allegations in paragraph 27 state legal conclusions to which no answer is required. To the extent that an answer is required, Defendants deny that the allegations accurately and completely recite the limitations of the claims recited in the '474 patent and, therefore, deny the allegations in paragraph 27.

28. Defendants admit that the FDA's Orange Book lists the '474 patent in connection with NDA No. 202611 with an expiration date of November 4, 2023. Defendants deny all other allegations in paragraph 28.

D. The '872 Patent

29. Defendants admit on information and belief that what purports to be a copy of U.S. Patent No. RE44,872 is attached to the Complaint as Exhibit D. Defendants further admit that Exhibit D is entitled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient" and lists April 29, 2014 as the Date of Patent. Defendants deny all other allegations in paragraph 29.

30. The allegations in paragraph 30 state legal conclusions to which no answer is required. To the extent that an answer is required, Defendants deny that the allegations accurately and completely recite the limitations of the claims recited in the '872 patent and, therefore, deny the allegations in paragraph 30.

31. The allegations in paragraph 31 state legal conclusions to which no answer is required. To the extent that an answer is required, Defendants deny that the allegations accurately and completely recite the limitations of the claims recited in the '872 patent and, therefore, deny the allegations in paragraph 31.

32. Defendants admit that the FDA's Orange Book lists the '872 patent in connection with NDA No. 202611 with an expiration date of November 4, 2023. Defendants deny all other allegations in paragraph 32.

E. Myrbetriq®

33. Defendants admit that Astellas Pharma Global Development Inc. is listed as the applicant holder for NDA No. 202611 for mirabegron extended-release oral tablets, 25 mg and 50 mg, on FDA's website, which also lists the products' proprietary name as Myrbetriq®. Defendants further admit that FDA's website lists the approval date for NDA No. 202611 as June 28, 2012 for both the 25 mg and 50 mg mirabegron extended-release oral tablets. Defendants further admit that the FDA's Orange Book lists the '117 patent, the '049 patent, the '474 patent, the '872 patent and U.S. Patent No. 6,346,532 ("the '532 patent") in connection with NDA No. 202611. The allegation in the third sentence that the '117 patent, the '049 patent, the '474 patent, the '872 patent and the '532 patent "cover[] the mirabegron compound and pharmaceutical compositions containing mirabegron" states a legal conclusion to which no answer is required. To the extent that an answer is required, Defendants deny that the third sentence accurately and completely recites the limitations of the claims recited in the '117 patent, the '049 patent, the '474 patent, the '872 patent and the '532 patent and, therefore, deny the allegation in the third sentence. Defendants deny all other allegations in paragraph 33.

34. Defendants admit that the chemical compound with the structure set forth in paragraph 34 has been referred to by the name mirabegron in the prescribing information for Myrbetriq® and has the IUPAC designation 2-(2-aminothiazol-4-yl)-*N*-[4-(2-{[(2R)-2-hydroxy-2-phenylethyl]amino}ethyl)phenyl]acetamide. Defendants lack knowledge or information

sufficient to form a belief about the truth of the remaining allegations in paragraph 34 and therefore deny them.

35. Defendants admit that, on information and belief, the label for Myrbetriq® extended-release oral tablets, 25 mg and 50 mg, available on the FDA website at http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202611s000lbl.pdf, includes the statement:

> **----------INDICATIONS AND USAGE----------**
> Myrbetriq is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency (1)

Defendants deny all other allegations in paragraph 35.

36. Defendants admit that Astellas Pharma Inc. is listed as the assignee of the '532 patent according to the patent assignment listings of the USPTO. Defendants further admit that Astellas Pharma Inc. is listed as the assignee on the face of the '117 patent, the '049 patent, the '474 patent and the '872 patent. Defendants deny all other allegations in paragraph 36.

37. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 37 and therefore deny them.

38. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 38 and therefore deny them.

F. Infringement by Zydus

39. Defendants admit that Zydus USA submitted ANDA No. 209488 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of mirabegron extended-release oral tablets, 25 mg and 50 mg. Defendants further admit that ANDA No. 209488 included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '117 patent, the '049 patent, '474 patent and the '872 patent. Defendants further

admit that the proposed labeling for ANDA No. 209488 complies with the required statutes and regulations. Defendants deny all other allegations in paragraph 39.

40. Defendants admit that Zydus USA submitted ANDA No. 209488 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of mirabegron extended-release oral tablets, 25 mg and 50 mg. Defendants deny all other allegations in paragraph 40.

41. Defendants admit that Zydus USA's September 6, 2016 letter states that Zydus USA submitted ANDA No. 209488 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of mirabegron extended-release oral tablets, 25 mg and 50 mg. Defendants further admit that Zydus USA's September 6, 2016 letter states that ANDA No. 209488 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '117 patent, the '049 patent, the '474 patent and the '872 patent and a detailed statement of the factual and legal bases upon which Zydus USA based the Paragraph IV Certification, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Defendants deny all other allegations in paragraph 41.

42. Defendants admit that Astellas Pharma Inc. is listed as the assignee of the '532 patent according to the patent assignment listings of the USPTO. The allegation that "[t]he '532 patent … claims the compound mirabegron and compositions containing mirabegron, which is the active ingredient of Myrbetriq®" states a legal conclusion to which no answer is required. To the extent an answer is required, Defendants deny that the allegation accurately and completely recites the limitations of the claims recited in the '532 patent and, therefore, deny the allegation. Defendants admit that Zydus USA submitted to FDA ANDA No. 209488 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of mirabegron

extended-release oral tablets, 25 mg and 50 mg. Defendants admit that ANDA No. 209488 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III certification") with respect to the '532 patent. Defendants deny all other allegations in paragraph 42.

43. Denied.

44. The allegations in paragraph 44 state legal conclusions to which no answer is required. To the extent that an answer is required, Defendants deny that paragraph 44 completely sets forth all provisions of the cited statute, regulations and other applicable law.

CLAIMS FOR RELIEF

COUNT I: DIRECT INFRINGEMENT OF THE '117 PATENT

45. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-44, as if fully set forth herein.

46. Denied.

47. Denied.

48. Denied.

COUNT II: DIRECT INFRINGEMENT OF THE '049 PATENT

49. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-48, as if fully set forth herein.

50. Denied.

51. Denied.

52. Denied.

COUNT III: DIRECT INFRINGEMENT OF THE '474 PATENT

53. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-52, as if fully set forth herein.

54. Denied.

55. Denied.

COUNT IV: INDUCEMENT TO INFRINGE THE '474 PATENT

56. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-55, as if fully set forth herein.

57. Defendants admit that the FDA's Orange Book lists the '474 patent in connection with NDA No. 202611. Defendants further admit that Zydus USA's September 6, 2016 letter states that ANDA No. 209488 included a Paragraph IV Certification with respect to the '474 patent and a detailed statement of the factual and legal bases upon which Zydus USA based the Paragraph IV Certification, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Defendants deny all other allegations in paragraph 57.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

COUNT V: CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT

65. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-64, as if fully set forth herein.

66. Defendants admit that Zydus USA submitted ANDA No. 209488 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of mirabegron extended-release oral tablets, 25 mg and 50 mg. Defendants deny all other allegations in paragraph 66.

67. The allegations in paragraph 67 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny all allegations in paragraph 67.

68. Denied.

69. Denied.

70. Denied.

COUNT VI: DIRECT INFRINGEMENT OF THE '872 PATENT

71. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-70, as if fully set forth herein.

72. Denied.

73. Denied.

COUNT VII: INDUCEMENT TO INFRINGE THE '872 PATENT

74. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-73, as if fully set forth herein.

75. Defendants admit that the FDA's Orange Book lists the '872 patent in connection with NDA No. 202611. Defendants further admit that Zydus USA's September 6, 2016 letter states that ANDA No. 209488 included a Paragraph IV Certification with respect to the '872

patent and a detailed statement of the factual and legal bases upon which Zydus USA based the Paragraph IV Certification, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv). Defendants deny all other allegations in paragraph 75.

76. Denied.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

COUNT VIII: CONTRIBUTORY INFRINGEMENT OF THE '872 PATENT

83. Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-82, as if fully set forth herein.

84. Defendants admit that Zydus USA submitted ANDA No. 209488 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of mirabegron extended-release oral tablets, 25 mg and 50 mg. Defendants deny all other allegations in paragraph 84.

85. The allegations in paragraph 85 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny all allegations in paragraph 85.

86. Denied.

87. Denied.

88. Denied.

PRAYER FOR RELIEF

Defendants specifically deny that Plaintiffs are entitled to the general or specific relief requested against Defendants, or to any relief whatsoever, and pray for judgment in favor of Defendants dismissing this action with prejudice, and awarding Defendants their reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer and without admitting any allegations of the Complaint not otherwise admitted, Defendants aver and assert the following Affirmative Defenses to Plaintiffs' Complaint.

FIRST AFFIRMATIVE DEFENSE

(Noninfringement of U.S. Patent No. 7,342,117)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, offer to sell, or importation into the United States of the proposed mirabegron extended-release oral tablets, 25 mg and 50 mg which are the subject of ANDA No. 209488 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '117 patent.

SECOND AFFIRMATIVE DEFENSE

(Invalidity of U.S. Patent No. 7,342,117)

Upon information and belief, the claims of the '117 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

THIRD AFFIRMATIVE DEFENSE

(Noninfringement of U.S. Patent No. 7,982,049)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, offer to sell, or importation into the United States of the proposed mirabegron extended-release oral tablets, 25 mg and 50 mg which are the subject of ANDA No. 209488 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '049 patent.

FOURTH AFFIRMATIVE DEFENSE

(Invalidity of U.S. Patent No. 7,982,049)

Upon information and belief, the claims of the '049 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

FIFTH AFFIRMATIVE DEFENSE

(Noninfringement of U.S. Patent No. 8,835,474)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, offer to sell, or importation into the United States of the proposed mirabegron extended-release oral tablets, 25 mg and 50 mg which are the subject of ANDA No. 209488 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '474 patent.

SIXTH AFFIRMATIVE DEFENSE

(Invalidity of U.S. Patent No. 8,835,474)

Upon information and belief, the claims of the '474 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

SEVENTH AFFIRMATIVE DEFENSE

(Noninfringement of U.S. Patent No. RE44,872)

Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, offer to sell, or importation into the United States of the proposed mirabegron extended-release oral tablets, 25 mg and 50 mg which are the subject of ANDA No. 209488 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '872 patent.

EIGHTH AFFIRMATIVE DEFENSE

(Invalidity of U.S. Patent No. RE44,872)

Upon information and belief, the claims of the '872 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

RESERVATION OF DEFENSES

Defendants hereby reserve any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

Dated: January 17, 2017

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CERTIFICATE OF SERVICE

I, Pilar G. Kraman, hereby certify that on January 17, 2017, I caused the foregoing to be electronically filed with the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that on January 17, 2017, I caused copies of the foregoing document to be served upon the following by e-mail.

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